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**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: Q96749

Ituro INOUE, *et al.*

Appln. No.: 10/591,454

Group Art Unit: 1645

Confirmation No.: 9372

Examiner: *Unassigned*

Filed: September 1, 2006

For: METHOD OF DETECTING CARCINOGENESIS CAUSED BY HEPATITIS B VIRUS

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after

INFORMATION DISCLOSURE STATEMENT  
U.S. Appln. No.: 10/591,454

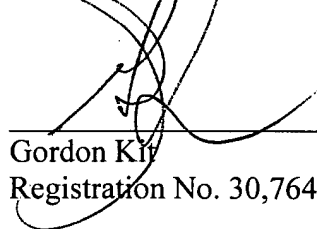
filing a request for continued examination (RCE) under § 1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

Applicants submit copies of the references previously cited in the Information Disclosure Statement filed on September 1, 2006, along with a copy of SB/08 Form listing cited references.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

  
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WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Date: December 29, 2006



MODIFIED PTO/SB/08 A & B (08-03)

Substitute for Form 1449 A & B/PTO  <b><u>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</u></b>  (use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	10/591,454
				Confirmation Number	9372
				Filing Date	September 1, 2006
				First Named Inventor	Ituro INOUE <i>et al.</i>
				Art Unit	1645
Examiner Name	Unassigned				
Attorney Docket Number	Q96749				
Sheet	1	of	1		

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code <sup>2</sup> (if known)		

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
		C.J. WALKER <i>et al.</i> , Identification of three novel cDNAs for human phosphatidylethanolamine N-methyltransferase and localization of the human gene on chromosome 17p11.2, <i>Biochim. Biophys. Acta</i> (1999), Vol. 59, pp. 187-192	
		L.J. CURTIS <i>et al.</i> , Amplification of DNA sequences from chromosome 19q13.1 in human pancreatic cell lines, <i>Genomics</i> (1998) 53, pp. 42-55	
		D. FERBUS <i>et al.</i> , Amplification and over-expression of OZF, a gene encoding a zinc finger protein, in human pancreatic carcinomas, <i>Int. J. Cancer</i> (1999), Vol. 80, pp. 369-372	
		T. URASHIMA <i>et al.</i> , Identification of hepatitis B virus integration in hepatitis C virus-infected hepatocellular carcinoma tissues, <i>Journal of Hepatology</i> (1997), Vol. 26, pp. 771-778	
		J.D. ROWLEY <i>et al.</i> , The critical role of chromosome translocations in human leukemias, <i>Annu. Rev. Genet.</i> (1998), Vol. 32, pp. 495-519	
		M. RUAULT <i>et al.</i> , MML3, a new human member of the TRX/MLL gene family, maps to 7q36, c chromosome region frequently deleted in myeloid leukaemia, <i>Gene</i> (2002), Vol. 284, pp. 73-81	
		M.J. FERBER <i>et al.</i> , Integrations of the hepatitis B virus (HBV) and human papillomavirus (HPV) into the human telomerase reverse transcriptase (Htert) gene in liver and cancers, <i>Oncogene</i> (2003), Vol. 22, pp. 3813-3820	
		S.Y. LIN <i>et al.</i> , Multiple tumor suppressor pathways negatively regulate telomerase, <i>Cell</i> (2003), Vol. 113, pp. 881-889	
		F. MITELMAN <i>et al.</i> , "A breakpoint map of recurrent chromosomal rearrangements in human neoplasia," <i>Nature Genetics</i> (1997), pp. 417-474	

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for Form 1449 A & B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	National Stage of PCT/JP2005/003383
				Confirmation Number	Unknown
				Filing Date	September 1, 2006
				First Named Inventor	Ituro INOUE
				Art Unit	Unknown
				Examiner Name	
Sheet	1	of	1	Attorney Docket Number	Q96749

## U.S. PATENT DOCUMENTS

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		US			
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## FOREIGN PATENT DOCUMENTS

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## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
		A. MARCHIO, ET AL., "RECURRENT CHROMOSOMAL ABNORMALITIES IN HEPATOCELLULAR CARCINOMA DETECTED BY COMPARATIVE GENOMIC HYBRIDIZATION", GENES CHROMOSOMES CANCER, 1997, VOL. 18, NO. 1, PAGES 59 TO 65	
		P.C. WANG, ET AL., "ANALYSIS OF INTEGRATED HEPATITIS B VIRUS DNA AND FLANKING CELLULAR SEQUENCE BY INVERSE POLYMERASE CHAIN REACTION", J. VIROL. METHODS, 2001, VOL. 92, NO. 1, PAGES 83 TO 90	
		D. G. HUNTSMAN, ET AL., "MLL2, THE SECOND HUMAN HOMOLOG OF THE DROSOPHILA TRITHORAX GENE, MAPS TO 19q13.1 AND IS AMPLIFIED IN SOLID TUMOR CELL LINES", ONCOGENE, 1999, VOL. 18, NO. 56, PAGES 7975-84	
		Y. Z. ZHOU, ET AL., "STRUCTURAL ANALYSIS OF A HEPATITIS B VIRUS GENOME INTEGRATED INTO CHROMOSOME 17p OF A HUMAN HEPATOCELLULAR CARCINOMA", J. VIROL, 1988, VOL. 62, NO. 11, PAGES 4224-31	
		P. PATERLINI-BRECHOT, ET AL., "HEPATITIS B VIRUS-RELATED INSERTIONAL MUTAGENESIS OCCURS FREQUENTLY IN HUMAN LIVER CANCERS AND CURRENTLY TARGETS HUMAN TELOMERASE GENE ONCOGENE", 2003, VOL. 22, NO. 25, PAGES 3911-6	
		D. GOZUACIK, ET AL., "IDENTIFICATION OF HUMAN CANCER-RELATED GENES BY NATURALLY OCCURRING HEPATITIS B VIRUS DNA TAGGING", ONCOGENE, 2001, VOL. 20, NO. 43, PAGES 6233-40	
		P. H. RAO, ET AL., "CHROMOSOMAL AMPLIFICATIONS, 3q GAIN AND DELETIONS OF 2q33-q37 ARE THE FREQUENT GENETIC CHANGES IN CERVICAL CARCINOMA", BMC CANCER, 2004.02, VOL. 4, NO. 1, PAGE 5	
		C. J. WALKEY, ET AL., "IDENTIFICATION OF THREE NOVEL CDNAS FOR HUMAN PHOSPHATIDYLETHANOLAMINE N-METHYLTRANSFERASE AND LOCALIZATION OF THE HUMAN GENE ON CHROMOSOME 17p11.2, BIOCHIM. BIOPHYS. ACTA, 1999, VOL. 1436, NO. 3, PAGES 405-12	
		K. T. FITZGERALD, ET AL., "MLL2: A NEW MAMMALIAN MEMBER OF THE TRX/MLL FAMILY OF GENES", GENOMICS, 1999, VOL. 59, NO. 2, PAGES 187-92	
		H. L. LIU, ET AL., "THE NOVEL ESTROGEN-RESPONSIVE B-BOX PROTEIN (EBBP) GENE IS TAMOXIFEN-REGULATED IN CELLS EXPRESSING AN ESTROGEN RECEPTOR DNA-BINDING DOMAIN MUTANT", MOL. ENDOCRINOL, 1998, VOL. 12, NO. 11, PAGES 1733-48	

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